

New Product Committee Guide

General Information

Name of Product: AccuTrac® Single-Use 200 micron Holmium Laser Fiber and Flexiva® TracTip High Power Single-Use 200 micron Holmium Laser Fiber

Product Codes:

Product Code	Description	Unit
M0068404110	AccuTrac 200 micron Holmium Laser Fiber	Single
M0068404112	AccuTrac 200 micron Holmium Laser Fiber	Box 5
M0068403960	Flexiva TracTip 200 micron Holmium Laser Fiber	Single
M0068403961	Flexiva TracTip 200 micron Holmium Laser Fiber	Box 5

Product Description:

The AccuTrac Laser Fibers are fiber optic laser energy delivery devices consisting of a SMA-905 connector, strain relief, and a silica core fiber jacketed with ethylene tetrafluoroethylene (ETFE). The Flexiva TracTip fibers are equipped with a polished and reinforced ball-shaped TracTip. These fibers may be used in a variety of laser based surgical cases as an integral part of laser systems.

The Flexiva TracTip Laser Fibers are fiber optic laser energy delivery devices consisting of a SMA-905 connector, strain relief, and a silica core fiber jacketed with ethylene tetrafluoroethylene (ETFE). The AccuTrac fibers are equipped with a polished and reinforced ball-shaped TracTip. These fibers may be used in a variety of laser based surgical cases as an integral part of laser systems.

Manufacturer: Boston Scientific Corporation

Distributor Federal Tax ID: 04 269 5240

Will this product(s) replace or supplement a current in-house product(s) now performing the same function?

The AccuTrac and Flexiva TracTip fibers will supplement the product line of AccuMax® and Flexiva® (End-Firing) single use Holmium Laser Fibers currently on the market.

Laser Compatibility:

AccuTrac Fibers are recommended for use with Ho:YAG laser systems with a standard SMA-905 connector that have been cleared for surgical use. Recommended Ho:YAG lasers are Dornier® and New Star. Please refer to the laser system User Manual for complete information regarding applications, contraindications, precautions and warnings.

Flexiva TracTip Fibers are recommended for use with Ho:YAG laser systems with a standard SMA-905 connector that have been cleared for surgical use. Recommended for use with Lumenis manufactured Ho:YAG and Nd:YAG lasers. Please refer to the laser system User Manual for complete information regarding applications, contraindications, precautions and warnings.

Product Usage

Briefly describe this product and other required components/accessories, specific items and their product numbers. Please include information as to whether in-house support is needed for use of product during OR cases.

Save Time and Procedural Steps with

AccuTrac & Flexiva TracTip Fibers



vs.

Typical Flat Tip Laser Fibers



Flat Tip Laser Fibers

According to the "Endourologic Use of the Holmium Laser", 2001 Demetrius Bagley, Akhil Das.

"The fiber (flat) tip can damage the channel within a flexible endoscope. Therefore, they must be passed only when the channel is straight. For example, to reach calculus within the lower pole of the kidney with a flexible ureteroscope, the tip should be straightened within the renal pelvis and the fiber passed. The fiber is advanced into the field of view and then withdrawn until it is just no longer visible. At that point, it will be located approximately ½ mm beyond the tip of the ureteroscope. The tip can then be deflected and placed into the lower pole for treatment. The fiber can then be advanced."¹

TracTip Laser Fibers

The ball shape tip is designed to reduce procedure steps associated with initial advancement of a deflected laser fiber to the treatment site. One step passage eliminates the need to re-access challenging stone locations.^{2,3}

**The fiber should not be re-passed through a deflected scope once laser energy has been applied to the treatment site.

AccuTrac® Single-Use Holmium Laser Fiber

Flexiva® TracTip High Power Single-Use Laser Fiber



Product Usage (cont.)

May reduce the risk of Flexible Endoscope Damage:

According to "Evaluation of a New 240 micron Single Use Holmium:YAG Optical Fiber for Flexible Ureteroscopy" – "No (Flexiva) fibers fractured during 100 consecutive ureteroscopy procedures. The lack of fiber fracture during clinical use may reduce the risk of flexible endoscope damage due to fiber failure."⁴

May reduce the risk of Laser Fiber Connector Failure:

According to "Evaluation of a New 240 micron Single Use Holmium:YAG Optical Fiber (Flexiva) for Flexible Ureteroscopy" – During 100 consecutive ureteroscopy procedures, "No (Flexiva) fibers failed at the connector end."⁵

Improved Scope Flexibility:

With a 242 micron core size, the AccuTrac and Flexiva TracTip Laser Fibers are designed to improve scope flexibility over larger core fibers (273 micron & 365 micron).⁶



According to the "Evaluation of 24 Holmium:YAG Laser Optical Fibers for Flexible Ureteroscopy,"

"We advocate using as flexible a fiber as possible to increase the likelihood that the stone can be reached and promote endoscope longevity."⁷

"Flexible ureteroscopy longevity directly correlates with time spent in the lower pole. Working in the lower pole results in stress and fatigue of the deflection mechanism, which leads to a loss of scope deflection and in some cases to scope failure. Therefore, fiber flexibility is an important variable in terms of accessing the stone and improving scope longevity. We advocate using as flexible a fiber as possible to increase the likelihood that the stone can be reached and promote endoscope longevity. While the difference between some fibers may be small, the benefit over multiple procedures may be cumulative."⁸

No additional in-house support is required, however, a brief in-service by a Boston Scientific Representative is offered at no-charge.

Documentation on studies conducted with product.

Journal of Endourology. 2011 November Volume 25, Supplement 1, Pages A118-119. Evaluation of a New 240 micron Single-use Holmium:YAG Optical Fiber for Flexible Ureteroscopy David M Shore, Michael Antiproda, Joel M Teichman, Bodo Knudsen

What quality or safety improvements to patient care could this product potentially provide?

The TracTip® Laser Fiber is designed to reduce procedure steps associated with initial advancement of a deflected laser fiber to the treatment site. One step passage eliminates the need to re-access challenging stone locations.

**The fiber should not be re-passed through a deflected scope once laser energy has been applied to the treatment site.

Cost/Utilization

Is this item/technology on contract with GPO's and/or IDN's?

Please speak to your Boston Scientific sales representative for the contract status of specific GPO's & IDN's.

Ship Unit: 1 **UOM:** Each

Mode of transportation: FedEx® Delivery

Minimum order quantity? No

Lead Time in working days? 1-2 days

What are the dimensions of the Product Carton?

The Product Carton for the fiber is 16" x 12"

What is the list price per each unit or unit of utilization?

Each = \$550.00

Box 5 = \$2,750.00

Method of Purchase: The purchase would be an outright purchase

Does this item require special storage considerations?

No, store in a cool, dry, dark place

Regulatory

Is this product FDA cleared for this intended use?

The AccuTrac Laser Fibers are intended for use in laser-based surgical applications, including but not limited to, endoscopic, laparoscopic and open surgical procedures involving vaporization, ablation and fragmentation of calculi (urinary and biliary) and surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection and incision of soft and cartilaginous tissue. The AccuTrac Laser Fibers are designed for use with Ho:YAG lasers with a standard SMA-905 connector that have been cleared for surgical use.

The Flexiva TracTip Laser Fibers are intended for use in laser-based surgical applications, including but not limited to, endoscopic, laparoscopic and open surgical procedures involving vaporization, ablation and fragmentation of calculi (urinary and biliary) and surgical procedures involving vaporization, ablation, coagulation, hemostasis, excision, resection and incision of soft and cartilaginous tissue. The Flexiva TracTip Laser Fibers are designed for use with Ho:YAG lasers with a standard SMA-905 connector that have been cleared for surgical use.

What is the FDA classification of this device?

The AccuTrac® Holmium Laser Fiber is marketed in the US in accordance with US 21 Code of Federal Regulations 878.4810 as a Laser Powered Surgical Instrument. Laser Fibers are Class II devices and are subject to the premarket notification (510k) process.

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Is this a dated product? Yes, with 3 year shelf life

Will this product require evaluation by any of the following departments?

- Epidemiology/Infection Control? No
- Bio Engineering Maintenance? No
- Safety and Security? No
- Pathology/Labs? No

Does this product contain metal substances that may affect tests and or procedures performed on patients? No

Does this item and its packaging contain no detectable latex? Yes

Is this product reusable? Single-Use

What additional waste or recycle costs are anticipated? None

Reimbursement

GuidePoint

Simplifying Reimbursement

Is this product reimbursable by insurance?

The procedure for which it is used is reimbursable. A billing guide with respective coding and Medicare reimbursement for Ureteroscopy with laser lithotripsy is available upon request. For additional coding and reimbursement information, contact your local Territory Manager or the Urology Reimbursement Help Desk at (508) 683-4022.

What is the Medicare Pass-Through Code (aka C-code or HCPCS)?

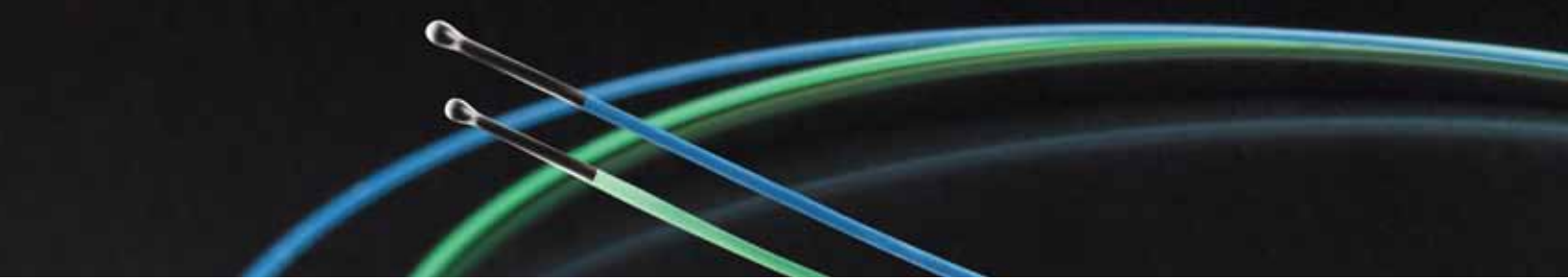
Through Code for this product is 52353 (Ureteroscopy with laser lithotripsy - ISWL).

Is this a patient-chargeable product?

Yes. The appropriate Revenue Code is 272 - Medical / Surgical Supplies and Devices – Sterile Supply. Medicare does not dictate a provider's charge structure or how it itemizes those charges. Section 2202.8 of the Medicare Provider Reimbursement Manual dealing with Ancillary Services (e.g. operating room) does not specifically address which items are part of the basic (routine) charge and which are charged in addition to the basic

charge. Medicare is on record that it is up to the individual hospital to determine whether to and how to itemize the charge for a specific supply. However, Medicare does require that charges billed on the CMS-1450 form (aka UB-04) be aggregated under the appropriate Revenue Code.





Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services and to submit appropriate codes, changes, and modifiers for services that are rendered. Boston Scientific recommends that you consult with your payers, reimbursement specialists and/or legal counsel regarding coding, coverage and reimbursement matters. Boston Scientific does not promote the use of its products outside their FDA-approved label.

¹ "Endourologic Use of the Holmium Laser", 2001 Demetrius Bagley, Akhil Das

² Bench Testing on file with Boston Scientific. Bench testing not necessarily indicative of clinical performance.

³ The fiber should not be re-passed through a deflected scope once laser energy has been applied to the treatment site.

⁴ *Journal of Endourology*, 2011 November Volume 25, Supplement 1, Pages A118-119. Evaluation of a New 240 micron Single-use Holmium: YAG Optical Fiber for Flexible Ureteroscopy David M Shore, Michael Antiproda, Joel M Teichman, Bodo Knudsen

⁵ *Journal of Endourology*, 2011 November Volume 25, Supplement 1, Pages A118-119. Evaluation of a New 240 micron Single-use Holmium: YAG Optical Fiber for Flexible Ureteroscopy David M Shore, Michael Antiproda, Joel M Teichman, Bodo Knudsen

⁶ Bench Testing on file with Boston Scientific. Bench testing not necessarily indicative of clinical performance.

^{7,8} *Journal of Urology*, 2009 July, Volume 182, Pages 348-354, "Evaluation of 24 Holmium:YAG Laser Optical Fibers for Flexible Ureteroscopy," Adam C. Mues, Joel M. H. Teichman and Bodo E. Knudsen

VersaPulse PowerSuite is a trademark of Lumenis, Inc.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician. Refer to package insert provided with the product for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using this product.

Boston Scientific

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